PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/US2004/010588	International filing date *(day/month/year)* 05.04.2004
Priority date *(day/month/year)* 08.04.2003	
International Patent Classification (IPC) or both national classification and IPC C07K14/47, G01N33/574	
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☒ contained in the international application as filed.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 26-38,42-44

because:

☒ the said international application, or the said claims Nos. 26-38,42-44 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2,3,5,7
	No:	Claims	1,4,6,8-46
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	2,3,5,7
Industrial applicability (IA)	Yes:	Claims	1-46
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

Re Item V.

The following documents are referred to in this communication:

D1 = Database accession no. ABG15488
D2 = Database accession no. AAS79675
D3 = Database accession no. AAE24066
D4 = Database accession no. AAD38831
D5 = WO99/67384
D6 = Database accession no. BC047903

1. Claims 26 to 38, and 42 to 44

For the assessment of the present claims 26 to 38, and 42 to 44 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment or diagnostic methods, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2. Novelty and Inventive Step (Articles 33(2) and 33(3) PCT)

2.1 Claims 1 to 25, 39 to 41, 45, and 46

Claims 1 to 25, 39 to 41, 45, and 46 are not new and/or inventive as required by Articles 33(2) and 33(3) PCT.

ABG15488 (D1) discloses a polypeptide that is 82% identical to the protein of SEQ ID NO:1 of the present application in an overlap of 883 amino acids. Since it cannot be excluded that the polypeptide of ABG15488 (D1) fulfils the functional criteria of claim 1(2), ABG15488 (D1) is regarded as being novelty-destroying for claims 1 and 4.

Correspondingly, the DNA sequence of AAS79675 (D2), encoding the polypeptide of ABG15488 (D1), has to be regarded as anticipating the subject-matter of claim 6. Of course, what has been said above holds also true for AAE24066 (D3) and AAD38831 (D4).

Even if claims 1, 4, and 6 were new, inventive step could not be acknowledged for these claims, like for all other claims.
Prostate cancer-associated genes and polypeptides were well known in the prior art from, e.g., WO99/67384 (D5) (see, e.g., the abstract).
Starting from this closest prior art, the technical problem underlying the present application could be seen in the provision of further prostate-specific proteins.
This problem is solved by providing the nucleic acid molecules/proteins of SEQ ID NOs: 2 and 1.
However, this solution is obvious in view of the disclosure content of BC047903 (D6). This document discloses a partial cDNA sequence encoding a human "prostate cancer associated protein 5" that is 100% identical to the 3'-terminal 461 nucleotides of the sequence of SEQ ID NO:2 of the present application. For solving the above technical problem, BC047903 (D6) thus provided an ideal starting point for the person skilled in the art: It provided the motivation since the cDNA was only partial, and certainly, there was also a reasonable expectation of success to isolate the full-length cDNA sequence.
It thus appears as if the person skilled in the art would have arrived at the claimed products without further ado.

Claims 8 to 25, 39 to 41, 45, and 46 represent standard molecular biology applications. Insofar as they are new over the cited prior art, they thus do not involve an inventive step.

Therefore, claims 1 to 25, 39 to 41, 45, and 46 do not comply with the requirements of Article 33(2) and/or 33(3) PCT.